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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,836	03/30/2006	Angelo Guglielmotti	281760US0PCT	6824
22850 7590 01/19/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER RAMACHANDRAN, UMAMAHESWARI	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/19/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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**Office Action Summary**

Application No.

10/560,836

Applicant(s)

GUGLIELMOTTI ET AL.

Examiner

Umamaheswari Ramachandran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-5 are pending.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "wherein R is cyclohexyl group" in line 2. There is insufficient antecedent basis for this limitation in the claim(1).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaster et al (EP 0630736) in view of Smith et al. (Neuroscience Letters, 271, 1999, 61-64) and further in view of Jorum et al. (Pain, 101, 2003, 229-235).

Gaster et al. teaches the compounds of formula I (claim 1) to be 5-HT4 antagonists (p1 lines 6-8) and further teaches a method of treatment of irritable bowel syndrome, migraine etc in mammals (p6, lines 42-43) comprising administering these compounds. The reference does not teach a method of treatment of neuropathic pain comprising administering such compounds.

Smith et al. teaches that 5-HT<sub>4</sub> receptor antagonist such as SB 207266 potentiates inhibition of intestinal allodynia (see Abstract, p63, lines 11-12).

The reference does not teach allodynia to be neuropathic pain.

Jorum et al. teaches that allodynia and hyperalgesia are frequent clinical findings in patients with neuropathic pain (p 229, lines 1-5).

It would have been obvious to one skilled in the art to use the compounds of formula I in the treatment of neuropathic pain. The motivation to do is provided by Smith et al. and Jorum et al. Smith et al. teaches that 5-HT<sub>4</sub> receptor antagonist such as SB 207266 shows an anti-allodynic activity and Jorum et al. teaches that allodynia and hyperalgesia are frequent clinical findings in patients with neuropathic pain. Hence inhibiting allodynia in patients provides a method of treatment of neuropathic pain.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaster et al (EP 0630736) in view of Burstein et al. (Brain, 2000, 123, 1703-1709) and further in view of Jorum et al. (Pain, 101, 2003, 229-235).

Gaster et al's teachings as above.

The reference does not teach a method of treatment of neuropathic pain comprising administering such compounds.

Burstein et al. teaches that most migraine patients exhibit cutaneous allodynia during a fully developed migraine attack (See Abstract).

The reference does not teach allodynia to be neuropathic pain.

Jorum et al. teaches that allodynia and hyperalgesia are frequent clinical findings in patients with neuropathic pain (p 229, lines 1-5).

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It would have been obvious to one skilled in the art to use the compounds of formula I in the treatment of neuropathic pain. The motivation to do is provided by Gaster et al, Burstein et al. and Jorum et al. Gaster et al teaches the administration of a 5-HT<sub>4</sub> antagonist is of potential benefit in relieving migraine attack. Burstein et al. teaches that cutaneous allodynia is exhibited during a fully developed migraine attack and Jorum et al. teaches that allodynia and hyperalgesia are frequent clinical findings in patients with neuropathic pain. Hence by treating migraine attacks in patients allodynia is treated and in turn the neuropathic pain.

### ***Conclusion***

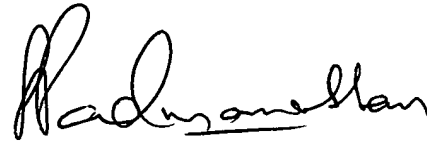
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**